

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*County of Lake, Ohio v. Purdue
Pharma L.P., et al.,*
Case No. 18-op-45032 (N.D. Ohio)

*County of Trumbull, Ohio v. Purdue
Pharma, L.P., et al.,*
Case No. 18-op-45079 (N.D. Ohio)

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

“Track 3 Cases”

WALMART INC.’S TRIAL BRIEF

Walmart submits this trial brief pursuant to the Court’s instructions, Doc. 3758 at 6, to summarize key facts and controlling law, as well as some of the most important evidentiary issues that Walmart anticipates arising during trial. This summary does not revisit the legal issues previously addressed to the Court, but Walmart anticipates renewing many of those arguments in appropriate motions at the close of Plaintiffs’ case and, if necessary, after trial. Walmart reserves the right to revise its trial presentation as the case develops.

Statement of the Facts

Plaintiffs do not allege that Walmart ever manufactured opioid medications or engaged in any sort of fraudulent activity. Instead, the only cause of action that Plaintiffs Lake County and Trumbull County pursue against Walmart is common-law absolute public nuisance, resting entirely on (1) Walmart’s distribution of prescription opioids to its own pharmacies and (2) Walmart pharmacists’ filling opioid prescriptions written by licensed medical professionals.

Extensive discovery has confirmed that Walmart does not belong in this litigation. Walmart's distribution and dispensing each accounted for a tiny share of the relevant market in Lake and Trumbull counties. Walmart self-distributed controlled substances to its pharmacies—and only to its pharmacies—until it stopped distributing controlled substances altogether in May 2018. Walmart's self-distributing accounted for only 3.48% of the prescription opioids distributed to Lake and Trumbull Counties, and the record shows that Walmart's anti-diversion distribution controls complied with the law at all times.

As for dispensing, all parties agree that Walmart pharmacies in Lake County or Trumbull County (or anywhere else) did not operate like the “pill mill” pharmacies alleged to have routinely filled clearly improper prescriptions for controlled substances. Walmart's five pharmacies dispensed only 3.3% of all of the prescription opioids dispensed by pharmacies in Lake and Trumbull Counties. By comparison, only three independent (nondefendant) pharmacies dispensed 17.2% of the opioids in the Counties—over five times as many as the five Walmart pharmacies.

Walmart also took steps to ensure proper dispensing of controlled substances at its pharmacies. Walmart hired only credentialed, trained, and licensed pharmacists. Walmart then provided multiple resources to further assist those pharmacists in dispensing controlled substances. It implemented systems, trainings, policies, and more in support of its pharmacists' exercise of professional judgment in dispensing controlled substances. Through things like Walmart's Pharmacy Operation Manuals (POMs), postings on Walmart's intranet, access to DEA and State Board of Pharmacy materials, Walmart training programs, and Walmart's databases, Walmart equipped its pharmacists with training and an abundance of information

about the patient, prescription, and prescriber so that its pharmacists could best exercise their professional judgment in dispensing prescriptions.

Moreover, regardless of Plaintiffs' allegations (and their experts' opinions) regarding the conduct of other actors in the supply chain of opioid medications, Plaintiffs have no basis to fault the Walmart pharmacists who, in accordance with their professional obligations, filled prescriptions written by doctors themselves acting in the usual course of their medical practice.

Nevertheless, Walmart understands that the Court will allow Plaintiffs to attempt to prove, as the draft jury instructions put it, that Walmart and the other Pharmacy Defendants' distribution and dispensing of prescription opioid medications caused "an oversupply of legal prescription opioids, and [] diversion of those opioids into the illicit market outside of appropriate medical channels, thereby endangering public health or safety." Doc. 3793-1 at 20. Plaintiffs will attempt to do so by positing several hindsight-based solutions, including sharing prescription data across pharmacies and cataloguing a series of overbroad "red flags." But those approaches misapprehend the relative responsibilities of the prescribing physician, the pharmacist, and the pharmacy when it comes to dispensing. Worse, they fail to distinguish legitimate from potentially illegitimate prescriptions, and Plaintiffs' putative rules would harm patients for whom opioid medications are medically necessary.

Controlling Law

This summary of controlling law includes legal issues that the Court has rejected in the context of earlier motions. Walmart presents them again to ensure preservation.

To start, the Ohio General Assembly has precluded Plaintiffs' suit several times over. The Ohio Product Liability Act ("OPLA") abrogates Plaintiffs' public nuisance claims because they are based on the distribution and dispensing of a product. Ohio Rev. Code

§ 2307.71(A)(13), (B). To the extent any claims survive OPLA’s enactment, such claims must satisfy the strict contours of a preexisting statute, *id.* § 4729.35. This statute directly addresses what remedies are available for a public nuisance action based on an alleged failure to adequately control against the diversion of drugs of abuse: Plaintiff Counties may bring an action in nuisance for alleged violations of the Ohio or federal Controlled Substances Acts (“CSAs”) seeking injunctive relief but cannot seek damages (or monetary relief couched as “abatement”) for violations of either CSA in an action for negligence.

Moreover, state tort liability is preempted when it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Arizona v. United States*, 567 U.S. 387, 399–400 (2012). In enacting the CSA, Congress struck a balance between protecting against the risk of diversion while ensuring that patients have the medications they need. *See* 21 U.S.C. § 801(1), (2); *Gonzales v. Raich*, 545 U.S. 1, 19, 24 (2005). Any application of state law that would stand as an obstacle to DEA’s ability to regulate and enforce that balance, or that would frustrate Congress’s purpose, is preempted—including the imposition of liability on any Pharmacy Defendant merely for distributing or dispensing opioids ordered by physicians in the usual course of professional treatment.

Even if Plaintiffs’ nuisance claim were not abrogated or preempted, Plaintiffs cannot prevail. The elements of an absolute public nuisance claim are (1) unreasonable interference with a public right (2) by conduct that was (i) inherently dangerous, (ii) intentional and culpable, or (iii) unlawful. *See, e.g., Barnett v. Carr ex rel. Est. of Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17, 2001). A public nuisance claim also requires proof of proximate causation. *See City of Cincinnati v. Deutsche Bank Nat’l Tr. Co.*, 863 F.3d 474, 480–81 (6th Cir. 2017); *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 502

(6th Cir. 2010); *Soukoup v. Republic Steel Corp.*, 66 N.E.2d 334, 335 (Ohio Ct. App. 1946). Ohio requires that a public nuisance claim involve invasion of a public right. *Brown v. Cnty. Comm'rs of Scioto Cnty.*, 622 N.E.2d 1153, 1158 (Ohio Ct. App. 1993). The right not to be negligently injured by a product or by another person's misuse of a product is a private right. *See State ex rel. Andersons v. Masheter*, 203 N.E.2d 325, 327 (Ohio 1964). Moreover, duly licensed individuals who engage in extensively regulated activities cannot be held liable for absolute public nuisance under Ohio law. *State ex rel. Schoener v. Bd. of Cnty. Comm'rs of Hamilton Cnty.*, 619 N.E.2d 2, 6 (Ohio Ct. App. 1992).

Should Plaintiffs somehow overcome each of these obstacles, they must still demonstrate that Walmart distributed or dispensed opioids in violation of the CSA. This they cannot do. As a distributor, Walmart was required to “operate a system to disclose to [Walmart] suspicious orders of controlled substances.” 21 C.F.R. § 1301.74. As a pharmacy, Walmart must employ licensed pharmacists. *Id.* § 1306.06. Those pharmacists may not “knowingly fill[]” a “prescription issued not in the usual course of professional treatment.” *Id.* § 1306.04(a). In addition, Walmart must comply with various physical-security requirements, *id.* §§ 1301.75, 1301.76. As both a distributor and a pharmacy, Walmart must adhere to certain recordkeeping requirements, *id.* § 1304.22(b), (c).

To prove liability under a dispensing-related theory, Plaintiffs must show that Walmart was “deliberately ignorant or willfully blind of the prescription information it ha[d].” Doc. 3499 at 6–8.¹ This demanding scienter standard far surpasses mere recklessness or negligence. To be

¹ Walmart preserves its objection to the motion-to-dismiss ruling and reiterates that the only duties that exist are those provided by the express mandates of the CSA and its regulations, and that the law requires Plaintiffs to show that Walmart pharmacists in fact filled prescriptions that they knew were not issued for a legitimate medical purpose. Even under the framework of this Court's ruling, however, Plaintiffs cannot prove their case.

“willfully blind,” a defendant must have taken “deliberate actions to avoid confirming a high probability of wrongdoing.” *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011) (citing G. Williams, *Criminal Law: The General Part* § 57, at 159 (2d ed. 1961); *see also Willful Blindness*, Black’s Law Dictionary (11th ed. 2019) (“Deliberate avoidance of knowledge.”). The defendant must have essentially “actually known the critical facts”—by “subjectively believ[ing] that there is a high probability that a fact exists” and by taking “deliberate actions to avoid learning of that fact.” *Glob.-Tech Appliances*, 563 U.S. at 769. To prevail at trial under this Court’s prior ruling, then, Plaintiffs must demonstrate that Walmart (1) believed its pharmacists were violating the CSA and (2) intentionally took actions to avoid learning about it. Plaintiffs cannot make this showing given Walmart’s repeated steps to ensure proper dispensing through trainings, systems, and controls.

In attempting to demonstrate otherwise, Plaintiffs will invoke agency adjudications as well as informal agency statements or publications and argue that Walmart’s failure to adhere to them demonstrates violations of the CSA and willful blindness. Two black-letter principles of administrative law control the legal effect that may be given to those documents. First, letters or other so-called “guidance” documents that express an agency official’s view of the law “do not have the force and effect of law and are not accorded that weight in the adjudicatory process.” *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995). Second, individual agency adjudications culminate in an order that is binding on the entity who is party to the adjudication, but they do not impose controlling legal requirements beyond that entity. Agency adjudications might formulate policy and provide a general guide to action the agency might be expected to take in a similar future matter, but this “is far from saying” what the law is, much less that the “commands, decisions, or policies announced in adjudication are ‘rules’ in the sense that they

must, without more, be obeyed by the affected public.” *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 (1969) (plurality op.).

In addition to demonstrating a violation of the Controlled Substances Act, Plaintiffs must prove causation for each Defendant individually. Under Ohio law, to recover against an individual defendant, Plaintiffs must prove that the “*particular defendant* caused [their] injur[ies]”—not just that their injuries are somehow traceable to the aggregated conduct of a group of defendants. *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998) (emphasis added). Even when the actions of multiple defendants have contributed to a single indivisible injury, establishing liability still requires plaintiffs to prove proximate causation “as to each defendant.” *Banas v. Shively*, 969 N.E.2d 274, 280 (Ohio Ct. App. 2011); *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990). Thus, even if Plaintiffs could show that defendants’ tortious conduct has contributed to a single, indivisible injury of “the opioid crisis,” Plaintiffs would still need to prove that the tortious conduct of Walmart individually was a “substantial factor” in producing the harm. *See Queen City Terminals, Inc. v. Gen. Am. Transp. Corp.*, 653 N.E.2d 661, 669 (Ohio 1995). Substantial factor causation requires more than mere evidence that a defendant may have contributed in some small way to the injury. *See Schwartz v. Honeywell Int’l, Inc.*, 102 N.E.3d 477, 481 (Ohio 2018). Given that Walmart accounted for only 3.48% of prescription opioids distributed to the Plaintiff counties and 3.3% of the prescription opioids dispensed there, Plaintiffs cannot demonstrate that Walmart’s conduct—much less Walmart’s tortious conduct (which, while Plaintiffs must prove such tortious conduct at trial, cannot include all of Walmart’s distribution and dispensing conduct)—alone had a “substantial impact” on the opioid crisis. *Id.* at 482.

Key Evidentiary Issues

Walmart anticipates that the most important evidentiary issues for the Court during trial may include the following:

- Plaintiffs' treatment of non-binding and sub-regulatory guidance documents by DEA employees as binding legal obligations, even if they are inconsistent with other guidance offered by different employees of the same agency.
- Efforts by Plaintiffs to obscure the varied and complex causes of the opioid crisis in Lake County and Trumbull County by limiting the admissibility of relevant evidence about them. In many instances, this evidence does not portray Plaintiffs and other government bodies and agencies in the best light. It also involves several actors absent from this trial, including well-intentioned prescribing doctors and criminal drug traffickers.
- Plaintiffs' attempts to conflate the evidence regarding different Pharmacy Defendants to create an aggregate case against a non-existent "industry" composed of differently situated pharmacies and other actors in the prescription opioid supply chain who were previously parties to these cases. Each Defendant's conduct, alleged contribution to the opioid crisis, and compliance with relevant legal requirements varies widely.
- Impermissible arguments by Plaintiffs that attempted collective proof can serve as evidence against each individual Defendant, even though Ohio law does not allow market-share liability.
- Efforts by Plaintiffs to overcome their lack of evidence of alleged conduct involving Lake County or Trumbull County by prejudicing the jury with the mere fact of civil investigations, criminal investigations, or settlements not involving Walmart and not

- concerning suspicious orders placed by pharmacies in Lake County or Trumbull County or the alleged improper dispensing of opioid medications in those counties. When ruling on the motions *in limine* filed for Track 1B, the Court made clear that “Plaintiffs may not point to the mere *fact* of a civil investigation as evidence of *liability*,” but instead only “to show other factors, such as a Defendant’s knowledge of its noncompliance, or to provide context as to why a Defendant took certain actions with respect to its suspicious order monitoring system (SOMS).” Doc. 3546 at 28. Significant trial time might be devoted to factual disputes lacking any relationship to Lake County or Trumbull County.
- Attempts by Plaintiffs to introduce evidence, testimony, or argument concerning alleged conduct that occurred outside Lake or Trumbull County without first establishing a specific nexus connecting that extraterritorial conduct to their claims, which are based on specific Defendants’ distribution and dispensing conduct and alleged harm suffered by the Counties. The Court previously held that “where evidence tends to show nation-wide trends and shipments, national policies and procedures, or systemic failures that are national in scope and become clear in the aggregate, the Court will *generally* permit such evidence.” *Id.* at 33. At the same time, “evidence that is specific in nature and does not have a nexus to the Plaintiff Counties, without more, will *generally* not be permitted.” *Id.* Significant trial time might be devoted to such extraterritorial factual disputes and line-drawing.
 - Walmart anticipates potential evidentiary disputes regarding the admissibility and relevance of “notes field” data for individual prescriptions. For example, the parties

may dispute whether a note written by a pharmacist who is not testifying at trial may be admitted. Significant trial time might be required to resolve related disputes.

Conclusion

Ohio law precludes Plaintiffs' absolute public nuisance claims. Even if it does not, and even if Plaintiffs could surmount the other threshold legal barriers to their claims, Plaintiffs bear the burden of proving that Walmart's self-distribution and dispensing conduct proximately caused their injuries and that this conduct was inherently dangerous, intentional *and* culpable, or unlawful. They cannot do so.

Dated: August 19, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via email on all counsel of record on August 19, 2021.

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